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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

IM62/0509

FINNEGAN HENDERSON FARABOW
GARRETT & DUNNER
1300 I STREET NW
WASHINGTON DC 20005

LIOTT, C

ART UNIT

PAPER NUMBER

1751

DATE MAILED:

05/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/319,204

Applicant

De La Mettrie et al.

Examiner
Caroline D. Liott

Group Art Unit
1751



☒ Responsive to communication(s) filed on Jun 30, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 32-74 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 32-74 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4.5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant's Preliminary Amendments filed 6/30/99 have been entered. Claims 1-31 have been canceled accordingly.

If bracketing is intended to appear in the claims of the published patent of the instant application (see e.g. claim 66), bracketing and underlining should not be used to indicate any future amendments or changes to the claims in order to avoid confusion during printing. See 37 CFR 1.121(a)(2)(ii).

Claims 66, 68, 70 and 72 are objected to because of the following informalities:

In claims 66, 68, 70 and 72, the term 2-(γ -methoxyethyl)amino-3-amino-6-methoxypyridine should read 2-(β -methoxyethyl)amino-3-amino-6-methoxypyridine.

In claims 68, 70 and 72, the term 4,5-diamino-1-(γ -hydroxyethyl)3-methylpyrazole should read 4,5-diamino-1-(β -hydroxyethyl)3-methylpyrazole.

In claims 66, 68, 70 and 72, the term 3,5-diamino-4-(γ -hydroxyethyl)amino-1-methylpyrazole should read 3,5-diamino-4-(β -hydroxyethyl)amino-1-methylpyrazole. Appropriate correction is required.

Claims 66, 68-70 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 66, 68, 70, 72 the term "the tautomeric forms thereof" lacks proper antecedent basis in the claims.

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In claims 68-70 the term "the desired coloration" lacks proper antecedent basis in the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-64, 66-68 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamahatsu.

Yamahatsu, EP 716,846, teaches and exemplifies various ready-to-use hair dyeing compositions which contain p-phenylenediamine, p-aminophenol as claimed, and m-aminophenol as claimed, the enzyme uricase, and the donor uric acid or potassium urate, wherein the compositions comprise solvents (e.g. water) as claimed, and have pH's as claimed, see Experiments 1, 4 and 5, and Examples 1, 5, 7 and 9. These compositions are applied to hair in

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dyeing processes as claimed. Yamahatsu teaches that the compositions may also contain direct dyes as claimed, see page 3, lines 16-20. Yamahatsu also teaches the equivalence between the claimed toluene-2,5-diamine and the exemplified p-phenylenediamine as oxidation dyes in the patentee's compositions, see page 3, lines 11-15. Yamahatsu does not exemplify a composition or process as claimed, particularly which contains or uses a p-phenylenediamine derivative as claimed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to at least partially substitute the p-phenylenediamine oxidation base in Yamahatsu's exemplified compositions identified above with 2,5-diaminotoluene as claimed, resulting in dyeing compositions and methods as claimed, because Yamahatsu teaches the equivalence between these compounds for use as oxidation dyes in the patentee's compositions, absent a showing otherwise.

Claims 32-64, 66-68 and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamahatsu as applied to claims 32-64, 66-68 and 74 above, and further in view of Husemeyer.

Yamahatsu is relied upon as set forth above as exemplifying hair dyeing compositions and processes similar to those as claimed (i.e. differing only in that they contain p-phenylenediamine rather than p-toluenediamine as claimed), and more broadly teaching compositions and processes as claimed. Yamahatsu teaches that the oxidation dyes which may be used in the patentee's compositions are not limited, see page 3, line 3. Yamahatsu's invention is directed towards improving the storage stability of uricase in hair dyeing compositions, see page 2, lines 18-21.

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Yamahatsu does not teach the specifically claimed 2- β -hydroxyethyl-p-phenylenediamine oxidation base.

Husemeyer, U.S. Patent No. 4,840,639, teaches hair dyeing compositions which comprise at least one 1-hydroxyalkyl-2,5-diaminobenzene, which encompasses the claimed 2- β -hydroxyethyl-p-phenylenediamine, see Abstract. The 1-hydroxyalkyl-2,5-diaminobenzene oxidation base may be combined with couplers, including those as claimed and as taught and exemplified by Yamahatsu (e.g. m-aminophenol), and other known developers (i.e. oxidation bases), see col. 1, lines 58-66 and col. 2, lines 17-19. Husemeyer teaches that when the patentee's 1-hydroxyalkyl-2,5-diaminobenzene's are used, various improved results are obtained such as improved solubility and shelf life, excellent fastness properties, improved toxicological and dermatological properties, and the possibility of attaining a wide range of tints, see col. 1, line 67- col. 2, line 2, and col. 3, lines 14-35. Also note the comparative Example wherein Husemeyer teaches that the combination of a 1-hydroxyalkyl-2,5-diaminobenzene and m-aminophenol results in a deeper color than that obtained when instead using a combination of Yamahatsu's 2,5-diaminotoluene and m-aminophenol, see col. 3, lines 46-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the p-phenylenediamine and p-toluenediamine oxidation bases in Yamahatsu's compositions (such as the Examples identified above) with 2- β -hydroxyethyl-p-phenylenediamine as claimed because Husemeyer teaches that the claimed oxidation base has good storage stability. Because Yamahatsu is primarily concerned with the storage stability of the patentee's

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compositions, those skilled in the art would have been motivated to make such a substitution. Furthermore, Husemeyer teaches other added benefits obtained when selecting the claimed oxidation base, such as improved fastness and toxicological properties, and improved color deepness as compared to when using Yamahatsu's oxidation bases, further motivating those skilled in the art to make such a substitution, absent a showing otherwise.

Claims 32-72 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotteret in view of Tsujino.

Cotteret, U.S. Patent No. 5,514,188, teaches compositions for dyeing hair which comprise a mixture of a p-phenylenediamine and/or bis(phenylenealkylenediamine) first oxidation base as claimed, a p-aminophenol second oxidation base as claimed, and the coupler 2-methyl-5-aminophenol or an acid addition salt thereof of claimed, see col. 1, line 55-col. 2, line 2, and col. 2, line 26-col. 4, line 26. The oxidation bases and couplers may be present in the claimed amounts at the claimed pH's, see col. 4, line 56-col. 5, line 2 and col. 5, lines 34-37. The compositions may contain solvents (e.g. water) as claimed, and direct dyes in order to enrich the glints, see col. 5, lines 51-55, and col. 6, lines 13-15. The compositions may be mixed with an oxidant just before application to the hair in a dyeing process as claimed, wherein preferred oxidants include hydrogen peroxide, see col. 4, lines 27-44, and col. 5, lines 7-10. The dye and oxidant compositions may be packaged in multi-compartment kits as claimed, see col. 4, lines 45-51. In Examples 1-6 Cotteret exemplifies compositions which comprise dye mixtures as claimed, which

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are mixed with a hydrogen peroxide oxidant before application to hair. Cotteret does not teach the claimed oxidoreductase enzymes and donors.

Tsujino, U.S. Patent No. 4,961,925, teaches compositions for dyeing hair which contain at least one dielectron reducing oxidase using oxygen as an acceptor (i.e. a 2-electron oxidoreductase enzyme as claimed), wherein Tsujino's preferred oxidases include those as claimed (e.g. uricase), see Abstract; col. 1, lines 46-54; and col. 2, lines 37-40. The enzymes are used in combination with a donor as claimed (e.g. uric acid), wherein the enzymes and donors may be present in the claimed amounts, see col. 2, lines 1-17. Tsujino teaches that when using the claimed enzyme/donor systems, satisfactory oxidizing results are achieved which have improved characteristics as compared to conventionally used oxidants (e.g. hydrogen peroxide) such as lower skin irritation and reduced damage to the hair and skin, see col. 1, lines 12-15 and 26-43; and Test Example 1 (see also Table 1). The enzyme/donor systems may be combined with any conventionally used oxidation dyes, including the oxidation bases and couplers as claimed and as taught by Cotteret, see col. 2, line 45-col. 3, line 3. Tsujino teaches that the enzyme/donor system is preferably combined with peroxidase as claimed, see Test Example 1 and Examples 4, 7, 8, 10, 11 and 12. The compositions may be packaged as two-compartment kits as claimed, and may be applied to hair in dyeing methods as claimed and as taught by Cotteret, i.e. wherein the oxidant and dye compositions are mixed just before use, see col. 2, lines 41-44, and Examples such as Example 9.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the hydrogen peroxide oxidants of Cotteret with an enzyme/donor system as claimed in the claimed amounts, wherein peroxidase may additionally be added, resulting in compositions, kits and dyeing processes as claimed, because Cotteret does not require the use of any specific oxidants, and Tsujino teaches that when the claimed enzymes and donors are used in place of conventional oxidants (such as Cotteret's preferred hydrogen peroxide) in compositions which contain any conventional oxidation dyes (including those taught by Cotteret and claimed), decreased skin irritation and damage to the hair and skin are obtained, absent a showing otherwise.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-65 of copending

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Application No. 09/319,165. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application recite ready-to-use hair dyeing compositions which contain 1) at least one first oxidation base chosen from p-phenylenediamines as instantly claimed; 2) at least one second oxidation base chosen from p-aminophenols as instantly claimed; 3) at least one m-aminophenol coupler chosen from 2-methyl-5-N-(beta-hydroxyethyl)aminophenol and acid addition salts thereof as instantly claimed; 4) at one 2-electron oxidoreductase enzyme; and 5) at least one donor as instantly claimed. The copending claims also recite corresponding hair dyeing processes and multi-compartment dyeing kits as instantly claimed. Therefore, the copending claims obviate the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Particularly note Cotteret, U.S. Patent No. 5,567,421, who like Cotteret '188 above, teaches hair dyeing compositions which contain a mixture of p-phenylenediamines and/or bis(phenylalkylenediamines), p-aminophenols and m-aminophenols as claimed, but uses a hydrogen peroxide oxidant.

Applicant is reminded that if any evidence is to be presented in accordance with 37 CFR 1.131 or 1.132, such evidence should be presented before final rejection in order to be considered timely.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caroline Liott whose telephone number is (703) 305-3703. The examiner can normally be reached on Mondays-Thursdays from 8:30am to 6:00pm, and on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Yogendra Gupta, can be reached at (703)308-4708. All before final official faxes should be sent to (703) 305-7718. All after final official faxes should be sent to (703) 305-3599. All non-official faxes should be sent to (703) 305-6078.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0661.

C.D.L.
May 3, 2000


CAROLINE D. LIOTT
PRIMARY EXAMINER